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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/814,354

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Rajesh V. Mehta

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02/08/2007

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EXAMINER

DRODGE, JOSEPH W

ART UNIT

PAPER NUMBER

1723

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

02/08/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.



Office Action Summary	Application No.	Applicant(s)	
	10/814,354	MEHTA ET AL.	
	Examiner	Art Unit	
	Joseph W. Drodge	1723	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11 December 2006</u> . | 6) <input type="checkbox"/> Other: _____ |

The terminal disclaimers filed on 11 December 2006 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of Applications 10/815,015 and 10/815,026 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claims 1-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The Specification fails to indicate how an impeller can be mounted in a particle formation vessel so as to impart both a highly agitated zone within one impeller diameter and also a bulk mixing zone at greater distances from the impeller. The Specification also fails to show how feed stream introduction ports can be configured and located relative to the impeller and impeller diameters, or structural relationships among introduction ports, mixing chamber and impeller agitator. The 3 patents referenced by the Specification at pages 10-12 in this regard only appear to give a single zone of mixing in impeller-containing vessels. There are no drawings in the instant application to provide clarity to the claimed combination of different mixing zones.

Claims 1-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed,

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had possession of the claimed invention. The Specification fails to indicate how an impeller can be mounted in a particle formation vessel so as to impart both a highly agitated zone within one impeller diameter and also a bulk mixing zone at greater distances from the impeller. The Specification also fails to show how feed stream introduction ports can be configured and located relative to the impeller and impeller diameters, or structural relationships among introduction ports, mixing chamber and impeller agitator. The 3 patents referenced by the Specification on pages 10-12 in this regard only appear to give a single zone of mixing in impeller-containing vessels. There are no drawings in the instant application to provide clarity to the claimed combination of different mixing zones.

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the claimed impeller, impeller diameters and configuration relative to location of 1st and 2nd stream introduction ports, and formation/configuration of different mixing zones relative to distance from the impeller surfaces and impeller diameters must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet,

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and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The disclosure is objected to because of the following informalities: The pending patent applications or issued patents referenced on page 14 of the instant specification must be identified by serial number and , if applicable by patent number or reference to their being abandoned, if applicable.

Appropriate correction is required.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saim et al patent 6,858,166 in view of Johnson et al PGPUBS Document US2004/0091546 and O'Conner et al PGPUBS Document US2006/0124783.

Saim et al disclose formation of micro or nano-particles by a process of admitting a supercritical fluid to a vessel, in which temperature and pressure are controlled (column 14, lines 21-45), agitating such vessel with a rotary agitator that may comprise an impeller of un-specified, given diameter relative to vessel diameter (column 14, line 63-column 15, line 6), introducing a 1st feed stream comprising a solvent and desired, active substance through a 1st introduction port and introducing a 2nd feed stream comprising the supercritical fluid through introduction ports both approximately within the highly agitated zone of the mixer that may be an impeller (see especially figures 1 and 2 and column 18, lines 30-63). Both a first feed stream including particle-forming

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components and solvent and a second feed stream containing the supercritical fluid may be introduced proximate the agitated/highly agitated zone of the mixer (see column 12, lines 11-12 taken with lines 33-36 of column 12). Particles are then precipitated within such vessel over a carrier bed. A major use of the Saim process is to produce a wide variety of pharmaceutical particles (column 6, lines 42-53).

The impeller or other agitator of the mixing vessel may be controlled to rotate at very high rotational speeds , so as to obtain high stirring intensity with vigorous stirring, hence induce turbulent mixing (column 12, lines 21-24, column 13, lines 50-51 and column 14, lines 30-32 and 62-65). Temperatures, pressures and other parameters are controlled to obtain optimum performance (column 11, line 57-column 12, line 2). Precipitated particles are formed to be of nanoparticle size , hence inherently of a volume-average diameter in the range of 100 nanometers or less (column 17, lines 5-8 and 54-67). The vessel inherently facilitates more rapid and more turbulent mixing in the immediate vicinity of the impeller agitators grading to less rapid and less turbulent/ bulk mixing in zones further away from the impeller.

The claims differ in requiring an explicit teaching of the particle formation and agitating vessel containing the impeller having two discrete mixing zones. However, O'Connor et al teaches to produce nanoparticles using solvents and supercritical fluids by use of conversion/mixing vessels that combine impeller mixers with other type stirrers, that have inlets for introducing solvents and other materials, and/or have a plurality of impeller mixers or impellers with differently functioning blades so as to create different mixing zones of different degrees of turbulence. See especially paragraph 33

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and paragraphs 22-32 and 38-40 are also pertinent. It would have been obvious to one of ordinary skill in the art to have adapted the more-complex configuration of mixing/agitating means of O-Connor in the process of Saim et al, to effect greater, more complete mixing of components which are in slurry form, or mixing of materials of different phases (liquids, solids, semi-solids and gases).

The claims also differ in requiring the feed stream introduction ports to be located within one impeller diameter of the surface of the impeller agitator. However, Johnson et al teach production of nanoparticles using supercritical fluid processing in which the inlet tubes are within 15% of the agitator surface diameter (see especially paragraph 44, paragraphs 39-42, 58 and 63 are also quite germane). It would have been further obvious to one of ordinary skill in the art to have located the end of the inlet tubes of Saim et al very close to the impeller agitators as suggested by Johnson et al, to facilitate rapid incorporation of the incoming fluid into the swept region of the agitator and rapid mixing.

Regarding dependent claims, Saim also discloses the following: for claims 3, 7 and 6, flow of particles exhausted to an expansion or collection chamber that may constitute a distributor (column 21, lines 10-17), use of capillaries for claim 5 (column 13, line 15), for claim 8 forming of a dispersion (column 6, line 34), for claims 9-14 forming of nanosize particles of relatively uniform particle size (column 17, lines 5-8 and column 7, lines 6-8), and for claims 15-18 forming of a wide range of pharmaceutical

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and industrial particles including the instantly claimed species (column 16, lines 33-45); paragraph 42 of O'Connor is also quite pertinent to claims 15-18.

Regarding claims 2 and 4, Saim discloses a steady-state operation of processing and agitation in the mixing/processing vessel (paragraph 14, lines 46-50) and illustrates a back-pressure regulator in the outlet from the processing vessel at the Mode 2 illustration of Figure 1. Also paragraph 42 of Johnson describes a steady-state operation with a maintained flow balance between incoming streams and collected streams.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Drodge at telephone number 571-272-1140. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can be reached at 571-272-1151. The fax phone number for the examining group where this application is assigned is 571-273-8300.

Applicant's arguments with respect to claims 1-18 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Drodge at telephone number 571-272-1140. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either private PAIR or Public PAIR, and through Private PAIR only for unpublished applications. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JWD

February 1, 2007


JOSEPH DRODGE
PRIMARY EXAMINER